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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,375	06/09/2000	Keiji Endo	2173-0120P	2206

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/590,375

Applicant(s)

ENDO ET AL.

Examiner

Elizabeth Slobodyansky, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-27 and 30-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-32, 36-38 and 43-46 is/are allowed.
- 6) ☒ Claim(s) 25-27, 33-35, 42 and 47 is/are rejected.
- 7) ☒ Claim(s) 39-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>herewith</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

5.0-0

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2005 has been entered.

The AF amendment filed June 21, 2005 amending claims 25-27, 30-35, 42, 43, 45 and 46 and adding claim 47 has been entered.

Claims 25-27 and 30-47 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 33-35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25, with dependent claim 26, has been amended to be directed to a mutation at a specific position of SEQ ID NO:1 "and optionally an additional substitution of an amino acid residue at 107th Met with another amino acid residue". New claim 47 is drawn to a mutant α -amylase obtained by introducing between 1 and 12 mutation(s) into SEQ ID NO:1 "and optionally an additional substitution of an amino acid residue at 107th Met with another amino acid residue". Therefore, claims 25 and 26 encompass mutant α -amylases having a double substitution comprising substitution at 107th Met and a substitution at any of the specific positions recited in the claims. In the case of claim 47, it can be combination of mutations at the specific positions and additionally at Met107th. Applicants indicate that the amendment is supported "by Example 8 starting at page 25 (Remarks of 6/21/05, page 8). However, the specification on pages 25-27 provides support for mutants having the specific combination of the specific mutations including M107L but not for a double mutation comprising M107L or any combination of mutations comprising M107th. Furthermore, the examiner is unable to locate adequate support in the specification for a substitution at 107th Met with an amino acid residue other than Leu.

Claims 33-35 recite combinations of mutations at the specific positions of SEQ ID NO:1 comprising M107 wherein the amino acid residue is substituted with another amino acid. While the specification provides support the combinations of mutations wherein the indicated residues are substituted with the specific amino acid (pages 24-27, Tables 3-5, 7), it does not provide support the substitutions at the indicated specific positions with any amino acid. Thus, there is no indication that the claimed mutant α -

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amylases were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27 and 42 recite "an amino acid sequence from 1st His to 21st Gly of SEQ ID NO:2" (emphasis added). Such language renders the claims unclear because said fragment is a single sequence and therefore should be recited as "the amino acid sequence from 1st His to 21st Gly of SEQ ID NO:2". Furthermore, inserting "the" before "N-amino terminal sequence" is suggested.

Allowable Subject Matter

Claims 30-32, 36-38 and 43-46 are allowed.

Claims 39-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed June 21, 2005 have been fully considered but they are not persuasive.

With regard to the 112, 1st paragraph rejection, Applicants argue that "referring to Example 8 starting at page 25 of the specification, Applicants point out that the 107th Met residue may be substituted with leucine, in combination with other mutations. Thus, as recited in the present claims, the combination substitution of the 107th Met with other possible substitutions is fully supported" (Remarks, page 9, emphasis added). As explained above, there is no support for a combination comprising 107th Met other than the specific combinations disclosed in the specification.

The previous 112, 1st and 112, 2nd rejections not reinstated in this Office action are withdrawn in view of the amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "E. Slobodyansky". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Elizabeth Slobodyansky, PhD
Primary Examiner
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August 18, 2005